CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761195Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Mitigation Assessment and Medication Error Surveillance (DMAMES)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	8/25/2021
Responsible OND Division:	Division of Neurology 1 (DN 1)
Application Type and Number:	IND 132953 BLA 761195
Product Name and Strength:	Vyvgart (efgartigimod alfa-fcab) injection 400 mg/20 mL (20 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	argenx BV (argenx)
FDA Received Date:	July 10, 2020 (IND) February 26, 2021 (BLA)
Nexus NPNS ID #:	2020-46 (IND) 2021-3 (BLA)
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
OMEPRM Deputy Director:	Lubna Merchant, MS, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by argenx for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761195.

1.1 Regulatory History

argenx was notified of the Agency's intention to designate a nonproprietary name that includes a four-letter distinguishing suffix that is devoid of meaning for their product in an Advice Letter[a].

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On July 10, 2020 (IND) and February 26, 2021 (BLA), argenx submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[b]. argenx also provided findings from an external study conducted by (b) (4) evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by argenx:

Table 1. Suffixes submitted by argenx***

1.	(b) (4)
2.	fcab
3.	(b) (4)
4.	
5.	
6.	

[a] Harris, D. General Advice Letter for BLA 761195. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Feb 18.

[b] Cover Letter – Request for Review of Proposed INN Suffixes BLA 761195. Zwijnaarde (Belgium): argenx BV; 2021 Feb 26. Available from: \\CDSESUB1\evsprod\bla761195\0009\m1\us\12-cover-letter\efg-usa-cover-letter-26feb2021.pdf

(b) (4)

7.	(b) (4)
8.	
9.	
10.	

We reviewed argenx's proposed suffixes in the order of preference listed by argenx, along with the supporting data they submitted, using the principles described in the applicable guidance.[a]

2.1 (b) (4)

(b) (4)

(b) (4)

(b) (4) the proposed suffix (b) (4) is not devoid of meaning, and is inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance[a].

We acknowledge that our evaluation differs from that of the external study performed by (b) (4) and submitted by the Applicant. However, the external study did not evaluate the suffix connotation (b) (4)

2.2 efgartigimod alfa-fcab

argenx's first proposed suffix, -fcab, is comprised of 4 distinct letters.

We determined that the proposed suffix -fcab, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is

[a] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMAMES' ANALYSIS

These findings were shared with OPDP. On August 24, 2021, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMAMES also communicated our findings to the Division of Neurology 1 (DN 1) on August 25, 2021.

4 CONCLUSION

We find argenx's proposed suffix -fcab acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to efgartigimod alfa-fcab. DMAMES will communicate our findings to the Applicant via letter.

4.1 Recommendations for argenx BV

We find the nonproprietary name, efgartigimod alfa-fcab, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, efgartigimod alfa-fcab will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we would inform you of our finding.

We also note that the first proposed suffix is unacceptable for the following reason:

1. (b) (4)

   We find your first proposed suffix, (b) (4) unacceptable. (b) (4) the proposed suffix (b) (4) is not devoid of meaning, and is inconsistent with the principles described in the Nonproprietary Naming of Biological Products guidance[a].

   We acknowledge that our evaluation differs from that of the external study performed by the (b) (4) However, the external study did not evaluate the suffix connotation of (b) (4)

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/s/

CARLOS M MENA-GRILLASCA
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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	March 15, 2021
Application Type and Number:	BLA 761195
Product Name and Strength:	Vyvgart (efgartigimod alpha-xxxx)[a] injection, 20 mg/mL
Total Product Strength:	400 mg/20 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	argenx BV
PNR ID #:	2020-1044395115
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Acting Team Leader:	Celeste Karpow, PharmD, MPH

[a] The proper name for Vyvgart has not yet been determined; therefore, “efgartigimod alpha-xxxx” is used as the proper name for this product.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Vyvgart, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Argenx BV did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Argenx BV previously submitted the proposed proprietary name, Vyvgart, under IND 132953 on February 7, 2020, and we found the name conditionally acceptable on July 7, 2020.[b]

Thus, argenx BV submitted the name, Vyvgart, for review on December 18, 2020.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 18, 2020.

- Intended Pronunciation: viv' gart
- Nonproprietary Name: efgartigimod alpha-xxxx
- Indication of Use: treatment of adult patients with myasthenia gravis
- Route of Administration: intravenous infusion
- Dosage Form: injection
- Strength: 20 mg/mL (400 mg/20 mL)
- Dose and Frequency: 10 mg/kg every 4 weeks (max 1,200 mg per infusion)
- How Supplied: Carton containing 1 single-dose vial
- Storage: Store VYVGART vials refrigerated at 2°C – 8°C (36°F-46°F) in the original carton to protect from light until time of use. (b) (4) DO NOT FREEZE. DO NOT SHAKE.

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Vyvgart.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Vyvgart would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis

[b] Morris, C. Proprietary Name Review for Vyvgart (IND 132953). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JUL 07. Panorama No. 2020-37743981.

(DMEPA) and the Division of Neurology 1 (DN 1) concurred with the findings of OPDP's assessment for Vyvgart.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Vyvgart.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[c].

2.2.2 Components of the Proposed Proprietary Name

Argenx BV did not provide a derivation or intended meaning for the proposed proprietary name, Vyvgart, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On January 15, 2021, the Division of Neurology 1 (DN 1) did not forward any comments or concerns relating to Vyvgart at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-five practitioners participated in DMEPA's prescription studies for Vyvgart. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

One CPOE participant provided the following comment: "wanted to type Vygart." We considered the participant's comment and determine there are no marketed products that begin with the letter string "vyg"; therefore, in this case, there is minimal risk for a name confusion medication error based on this response.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified twenty-three names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated all of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we did not identify any names not previously analyzed.

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[c] USAN stem search conducted on February 4, 2021.

[d] POCA search conducted on February 4, 2021 in version 4.4.

2.2.6 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

There are no new names to assess for this review.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology 1 (DN 1). At that time, we also requested additional information or concerns that could inform our review. On March 3, 2021, the Division of Neurology 1 (DN 1) provided the following comments: *"The clinical team noted a concern that the name is similar to Vyepti. Vyepti is an infusion given for migraine, and Vyvgart is an infusion given for MG. The concern is that patients with neurological disorders will go to an infusion center, and the ordering physician or pharmacist may confuse these products".*

We considered this comment and determine there is low risk for name confusion to result in wrong drug errors because the name pair has sufficient orthographic and phonetic differences.

Orthographically, the name pair does not contain a shared letter string of three or more letters[e], and the suffixes (-art vs -ti) provide some differentiation.

Phonetically, the first syllables (viv' vs vye) and second syllables (gart vs ep') sound different. Additionally, Vyepti contains an extra syllable.

Our assessment is supported by the FDA Phonetic and Orthographic Computer Analysis (POCA) software, which calculates a combined phonetic and orthographic score of 38% for this name pair, which suggests that the names have low similarity.

On March 9, 2021, we notified DN 1 that we considered their comments and maintain the name, Vyvgart, is acceptable.

3 CONCLUSION

The proposed proprietary name, Vyvgart, is acceptable.

If you have any questions or need clarifications, please contact Casmir Ogbonna, OSE project manager, at 301-796-5272.

3.1 COMMENTS TO ARGENX BV

We have completed our review of the proposed proprietary name, Vyvgart, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on December 18, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[e] Drug name pairs that contain a shared letter string of at least 3 letters are a major contributing factor in the confusion of drug names.

See the following for more information about shared letter strings: Shah, MB, L Merchant, IZ Chan et al., Characteristics that may help in the identification of potentially confusing proprietary drug names, Therapeutic Innovation and Regulatory Science, 51(2): September 2016.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [f]

[f] National Coordinating Council for Medication Error Reporting and Prevention. https://www nccmerp.org/about-medication-errors Last accessed 10/05/2020.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[g]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

[g] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

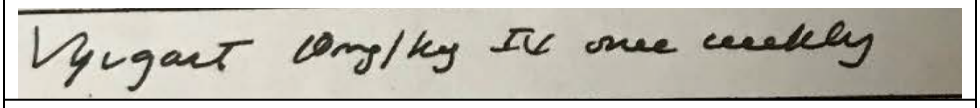
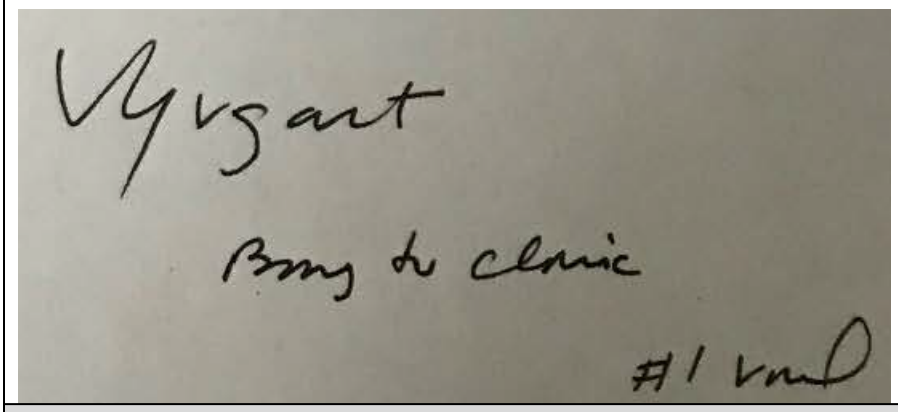
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Vyvgart Study (Conducted on December 29, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  Outpatient Prescription:  **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** Vyvgart	Vyvgart Bring to clinic #1 vial

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Vyvgart
As of Date 2/4/2021

209 People Received Study
75 People Responded

Study Name: Vyvgart

Total	14	28	17	16	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
VGUGART	0	0	0	2	2
VIGUART	0	0	1	0	1
VISCART	0	0	1	0	1
VISGART	0	0	1	0	1
VIVGART	0	0	7	0	7
VIZGART	0	0	1	0	1
VYLGART	0	0	0	1	1
VYUGART	0	0	0	6	6
VYVGAIT	0	0	0	1	1
VYVGANT	1	0	0	0	1
VYVGART	10	28	0	6	44
VYVGASTG	1	0	0	0	1
VYVSART	1	0	0	0	1
VYZGANT	1	0	0	0	1
ZIMVARP	0	0	1	0	1
ZIVGART	0	0	3	0	3
ZIVGUART	0	0	1	0	1
ZYVGARET	0	0	1	0	1

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/s/

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